K110349

MAY - 3 2011

510(k) SUMMARY STATEMENT

This 510(k) summary is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990, 21 CFR 807.92

1. **General Information**

Date of Submission: February 4, 2011

Submitted By: Solta Medical, Inc.
25881 Industrial Blvd
Hayward, CA 94545

Contact Person: Kristine Foss
V.P., Regulatory, Clinical & Quality
510-780-4657 (Direct Phone)
510-780-4857 Fax
kfoss@solta.com

2. **Trade/Proprietary Name of Device:**

Trade Name:	CLEAR+BRILLIANT™ Laser System
Common Name:	Laser Surgical Instrument
Regulation Number	878.4810
Product Code:	GEX
Device Panel:	General Surgery/Restorative Devices
Device Classification:	Class II

3. **Legally Marketed Predicate Device for Claimed Equivalence:**

Name: Fraxel IV SR Laser System
510(k) #: K063808

4. **Device Description**

The CLEAR+BRILLIANT™ Laser System is a non-ablative laser system designed for use in non-invasive dermatological procedures.

The CLEAR+BRILLIANT™ Laser System has a laser source in the hand piece which is controlled by an embedded processor. The console is electrically connected to the facility power source. Laser energy produced by the unit is delivered to the tissue through the removable (disposable) contact treatment tips which attach to the hand piece.

4. **Indications for Use:**

Dermatological procedures requiring the coagulation of soft tissue and general skin resurfacing procedures.

5. **Technological Performance Data:**
The CLEAR+BRILLIANT™ Laser System is compliant with ISO 60601-1 for electrical safety, IEC 60601-1-2 for EMI/EMC, ISO 60825 and 10993-1 for biocompatibility of the treatment tips.

Histology confirms the treatment skin response is the same as for the predicate Fraxel IV SR laser system when used at the same energy density settings.

The difference between the CLEAR+BRILLIANT™ device and its predicate is that the CLEAR+BRILLIANT™ device is operated at pre-determined energy settings (the lower end of the range in the predicate); not user selectable settings, as in the predicate.

6. **Summary Statement:**
With the same intended use, same patient population, same setting (wavelength, spot-size, fractional treatment and pattern of micro treatment zone punctures, same optical tracking system, and histological outcome), the CLEAR+BRILLIANT™ laser system is equivalent to the Fraxel IV SR laser system. Based upon the passing test results for laser safety and electrical safety, as well as biocompatibility and histology, when compared to the predicate, the CLEAR+BRILLIANT™ laser raises no new safety and effectiveness questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY - 3 2011

Solta Medical, Inc.
% Ms. Kristine Foss
V.P., Regulatory, Clinical & Quality
25881 Industrial Boulevard
Hayward, California 94545

Re: K110349
Trade/Device Name: CLEAR+BRILLIANT™ Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: ONG
Dated: April 5, 2011
Received: April 7, 2011

Dear Ms. Foss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110349

Device Name: CLEAR+BRILLIANT™ Laser System

Indications For Use:

Dermatological procedures requiring the coagulation of soft tissue and general skin resurfacing procedures.

Prescription Use X AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110349